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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,429	02/13/2002	Rosa Martani	3-31105A	8742

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,429	MARTANI, ROSA	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time and Amendment filed 12/13/04.

Double Patenting

Non-statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,083,531 ('531), in view of US 4,311,490 ('490). Although the conflicting claims are not identical, they are not patentably distinct from each other because '531 claims a solid pharmaceutical dosage form comprising active substance, filler, binding agent, and usual auxiliaries. The solid dosage form is disintegrates in the mouth within 15 seconds (claim 1). Filler and binder are found in claims 2. The density of the dosage form is found in claims 3 and 4. The amounts of the ingredients are found in claims 7 and 8.

Lubricant is found in claim 12. The '531 patent does not claim the claimed disintegrant, including polymethylmethacrylate (claim 13), however, '531 claimed binding agent and usual auxiliaries (claim 1). The '490 patent discloses binder such as polymethylmethacrylate (column 5, line 4). Therefore, those of ordinary skill would expect a similar quick dissolve solid dosage form having the claimed disintegration time from the use of the instant invention given the claims of the '531 and the '490 patents. There are no unusual and/or unexpected results, which would rebut prima facie obviousness. As such, the instant claims would have been obvious given the claims of the '531 and '490, which set out a similar quick dissolve dosage form using similar ingredients.

Response to Arguments

Applicant's arguments filed 12/13/04 have been fully considered but they are not persuasive. The examiner maintains the double patenting rejection.

Applicant argues that there is no case of prima facie obviousness because the '490 patent is directed to an abrasive cutting tool, and it does not even teach any composition that can be ingested or even dissolved in aqueous medium. Given that the '490 patent is directed to an abrasive cutting tool whereas the present claims are directed to a pharmaceutical composition, there is no motivation to select an isolated teaching of a binder for an abrasive composition and combine with a pharmaceutical composition. In response to applicant's argument that the '490 patent is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's

endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The '490 patent is relied upon solely for the teaching that polymethylmethacrylate is a known binding agent, and therefore, those of ordinary skill would expect a similar quick disintegrate formulation from the use of the instant invention given the claims of '531 and binding agent such as polymethylmethacrylate. Accordingly, the obviousness-type double patenting rejection is maintained.

Claim Rejections - 35 USC § 112

The 112, first paragraph rejection of claims 1-11 has been withdrawn in view of applicant's remark dated 12/13/03 at page 9. Applicant states that when an active substance is not included in step (a), the active substance is added to the final composition by adding the active to the solvent, which is combined with the component of step (a) in a later step.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. WO 97/38679.

Humbert-Droz teaches process for preparing fast disintegrating oral dosage form discloses in pages 5-6. It appears that Humbert-Droz is silent as to the teaching of compacting a suitable amount of the prepared powder or granulate as claimed in step (c). However, it is the position of the examiner that no criticality is seen in the particular step, since the prior art obtains the same result desire by the applicant, e.g., fast disintegrating oral dosage. Although, Humbert-Droz does not teach compacting the prepared powder or granulate, the extra step does not impart patentability over the applied prior art. Applicant's desire to produce rapidly dissolving dosage form, Humbert-Droz produces rapidly dissolving oral dosage form. Thus, it would have been prima facie obvious for one of ordinary skill in the art to, by routine experimentation modify Humbert-Droz with the expectation of similar result, because Humbert-Droz teaches a rapidly dissolving oral dosage form having the same density and the same disintegrating time. With regarding to the composition claims, it is the position of the examiner that one of ordinary skill in the art would have been motivated to modify Humbert-Droz's composition to obtain the claimed invention because Humbert-Droz

teaches a rapidly dissolving oral dosage form having the claimed density of 200-1000 mg/ml, and disintegrating time of within 15 seconds (pages 2-5).

Claims 13-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. WO 97/38679, in view of Erdos et al. US 5,108,757.

Humbert-Droz teaches fast disintegrating oral dosage form comprising active agent, filler, binding agent (disintegration agent), and talc as lubricant pages 3-4, and claims 1-13. The dosage form can be a tablet, which disintegrate in the mouth within 15 seconds, and have a density of 200-1000 mg/ml (pages 5-6). The dosage form is prepared without applying any freeze-drying, or any compression force (page 5).

Humbert-Droz does not teach the claimed disintegrant. However, Humbert-Droz teaches the use of other auxiliaries.

Erdos teaches a tablet dosage form comprising known auxiliary agents, including talc, magnesium stearate, and croscarmellose (column 5, lines 5-11). Thus, it would have been obvious for one of ordinary skill in the art to modify the auxiliary agents of Humbert-Droz using the croscarmellose as a disintegrant agent in view of the teaching of Erdos with the expectation of providing a quick dissolve tablet useful in pharmaceutical art.

Claims 13-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. WO 97/38679, and Bovenkerk et al. US 4,311,490.

Humbert-Droz is relied upon for the reasons above. Humbert-Droz does not teach the claimed disintegrant. However, Humbert-Droz teaches the use of binder.

Bovenkerk teaches binder such as polymethylmethacrylate (column 5, lines 4-5). Thus, it would have been obvious for one of ordinary skill in the art to modify the tablet composition of Humbert-Droz using the polymethylmethacrylate as a binding agent in view of the teaching of Bovenkerk with the expectation of providing a quick dissolve tablet useful in pharmaceutical art.

Response to Arguments

Applicant argues that Humbert-Droz does not teach an additional step of placing the compacted powder or granulate in a solvent, thus, there is no suggestion in Humbert-Droz that any compacted mass of the ingredient can be produced for any reason. However, assuming *arguendo* that it appears that Humbert-Droz does not teach the additional step, applicant has not established the criticality in the claimed additional step since Humbert-Droz obtains the same result desire by the applicant, e.g., fast disintegrating oral dosage using a similar method. Furthermore, what is the criticality in the additional step, when it is just a waste of efforts and has no benefit but added burdens?

Applicant argues that there is no motivation to combine Humbert-Droz and Erodes because Erdos is directed to a tablet that has nothing to do with a fast dissolving tablet. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Erdos is relied upon solely for the teaching of known auxiliary agents in tablet dosage form, including talc, magnesium stearate, and croscarmellose Humbert-Droz does not teach the claimed disintegrant

Applicant argues that there is no motivation to combine the abrasive tool binder of the '490 patent to a pharmaceutical composition of Humbert-Droz. In response to applicant's argument that the '490 patent is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The '490 patent is relied upon solely for the teaching that polymethylmethacrylate is a known binding agent, and therefore, those of ordinary skill would expect a similar quick

disintegrate formulation from the use of the instant invention given the claims of '531 and binding agent such as polymethylmethacrylate.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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